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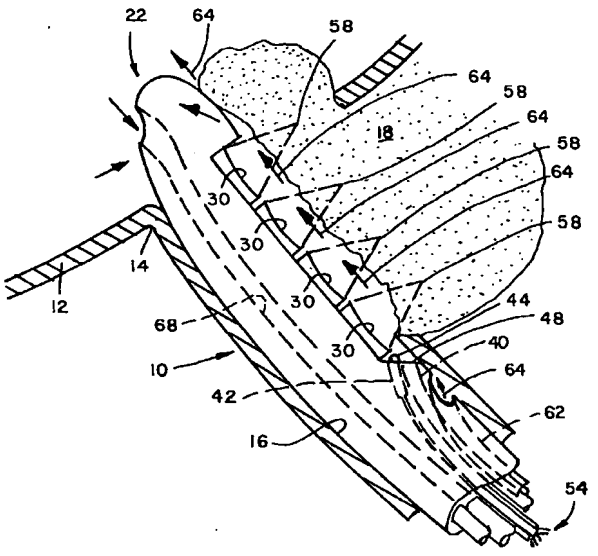
(54) Title: ABLATION SYSTEM WITH VISUALIZATION



(57) Abstract: A method of treating tissue includes (a) providing a catheter (10) having proximal (20) and distal (22) ends, a lumen extending between the proximal and distal ends, multiple ultrasound transducers (30) adjacent the distal end (22), the transducers (30) capable of transmitting sufficient power of high intensity focused ultrasound (HIFU) therapy, and a device (60) for monitoring the temperature adjacent the transducers, (b) orienting the transducers (30) adjacent the treatment region, (c) exciting the transducers (30) to treat the tissue, and (d) flushing fluid over the transducers (30). Apparatus for treating tissue includes the catheter (10), the device (60) for monitoring the temperature adjacent the transducers (30), at least one transducer driver (74) for exciting the transducers (30) to treat the tissue, and a source providing a flow of fluid through the lumen and over the transducers (30).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ABLATION SYSTEM WITH VISUALIZATION

Field of the Invention

This invention relates to medical treatment with ultrasound. It is disclosed in the context of a system for the treatment of prostate disease, but is believed to be useful in other applications as well.

Cross-Reference to Related Applications

This application claims priority to U.S.S.N. 60/200,312, filed April 28, 2000, the disclosure of which is hereby incorporated herein by reference.

Background of the Invention

A number of different ultrasound treatments for disease are known. There are, for example, the systems illustrated and described in U.S. Patents Nos.: 5,676,692; 4,586,512; 5,149,319; 5,840,031; 5,080,102; 5,295,484; 5,492,126; 5,873,902; and 5,018,508, and WO 99/49788, the disclosures of which are hereby incorporated herein by reference. No representation is intended that a complete search has been made of the prior art or that no better art references are available, and no such representation should be inferred. This listing shall not be construed to be an admission that the listed references are, or are considered to be, material to patentability.

Disclosure of the Invention

According to one aspect of the invention, the region of a catheter, such as a urological catheter, adjacent the remote end of the catheter is provided with one or more small ultrasound transducers capable of transmitting sufficient power at appropriate frequencies in one or more modes of operation for ultrasound visualization and high intensity focused ultrasound (HIFU) therapy.

Illustratively according to this aspect of the invention, the therapeutic ultrasound is at frequencies and powers capable of achieving treatment by one or the other or both of HIFU-induced tissue ablation and cavitation.

Further illustratively according to this aspect of the invention, treated tissue is reabsorbed by the body over a relatively longer period of time.

Additionally or alternatively illustratively according to this aspect of the invention, if cavitation is the mechanism of treatment, treated tissue is mechanically destroyed.

Illustratively according to this aspect of the invention, a mechanism, such as a flushing fluid flow or irrigation with or without a continuous vacuum assist, is provided to remove the debris occasioned by the cavitation debridement. As an alternative to continuous vacuum assist, a flushing fluid flow may be directed into the body of the patient undergoing treatment, for example, toward the bladder of a patient undergoing treatment of the prostate, for example, to flush debris into the bladder. The tissue debris may, for example, then be removed during treatment with or without the application of a vacuum, or after treatment when the patient's bladder is voided.

Further illustratively according to this aspect of the invention, the visualization may be optical, for example, by providing an optical fiber in the catheter and providing a light source adjacent the distal end of the optical fiber, that is, the end inside the urethra. The light source may be, for example, a second optical fiber provided with light from a source at the proximal end of the catheter, or may be a light emitting diode (LED) adjacent the distal end of the catheter powered by an electrical source at the proximal end of the catheter via conductors which extend along the length of the catheter from its proximal end to its distal end.

Additionally or alternatively illustratively according to this aspect of the invention, the visualization may be by means of one or more of the ultrasound transducers driven in, for example, a pulse-echo mode to provide (an) ultrasound image(s) of the progress of the treatment. The ultrasound image(s) can be converted by known techniques into (a) video image(s). Such visualization mechanisms permit the progress of the treatment to be monitored, regardless of the mechanism of treatment.

Illustratively according to this aspect of the invention, the catheter can be of any of a number of suitable types, including catheters with stiffening members, braided catheters and catheters with braided sheaths to permit the transmission of torque down the length of the catheter. This aids in the manipulation of the remote

end of the catheter, including the transducer(s) into various orientations necessary for effective visualization and therapy.

Further illustratively according to this aspect of the invention, a device is provided adjacent the or each transducer for monitoring the temperature adjacent the or each transducer. Illustratively, the temperature monitoring device includes a thermocouple oriented adjacent the or each transducer.

Brief Description of the Drawings

The invention may best be understood by referring to the following detailed description and accompanying drawings which illustrate the invention. In the drawings:

Fig. 1 illustrates a partly fragmentary sectional side elevational, partly block and partly schematic diagram of a detail of a system constructed according to the invention in place for HIFU and/or cavitation-inducing treatment of a prostate;

Fig. 2 illustrates a partly fragmentary view of a detail of another system constructed according to the invention;

Fig. 3 illustrates a block diagram of a detail of a system constructed according to the invention;

Fig. 4 illustrates a partly block and partly schematic diagram of a detail of another system constructed according to the invention;

Fig. 5 illustrates a partly block and partly schematic diagram of a detail of another system constructed according to the invention;

Fig. 6 illustrates a partly block and partly schematic diagram of a cross-section taken along lines 6-6 of Fig. 4;

Fig. 7 illustrates a partly block and partly schematic diagram of a cross-section of a detail of another system constructed according to the invention;

Fig. 8 illustrates a detail of another system constructed according to the invention; and

Fig. 9 illustrates a detail of another system constructed according to the invention.

Detailed Descriptions of Illustrative Embodiments

Referring now to Figs. 1-4, transurethral catheters 10 are provided for use in patients suffering from benign prostate hyperplasia (BPH) or prostate cancer. Fig. 1 illustrates a lower portion of a bladder 12, a bladder neck 14, and an upper portion of a urethra 16 of such a patient. Directly beneath the bladder 12 and around the bladder neck 14 is the patient's diseased prostate tissue 18. As best illustrated in Fig. 2, the diseased tissue 18 can grow into the bladder 12. The catheters 10 can be constructed from, for example, live or synthetic rubber or other materials from which urological catheters are customarily constructed.

Catheter 10 includes a proximal end 20 and a distal end 22. As illustrated in Fig. 1, catheter 10 may include a balloon 24 located at the distal end 22 to aid in positioning the catheter 10 relative to the prostate tissue 18. Catheter 10 further includes one or more lumens, as best illustrated in Figs. 6-7, for the various services which are delivered in any given catheter 10 to its distal end 22, and for any signals, material, and so on, which is returned to its proximal end 20. A number, illustratively three or four, of small ultrasound transducers 30 are provided adjacent the distal end 22 of catheter 10. Catheter 10 is sufficiently ruggedly constructed to permit manipulation of the transducers 30 into the orientations necessary to treat the prostate 18 in the manner which will be described. Once properly positioned, the transducers 30 are excited through appropriate electrical conductors which extend through a lumen 26.

Referring to Fig. 1, the proximal end 20 of catheter 10 is provided for attachment through a coupler 32 (illustrated diagrammatically) to one or more of the various services, such as a light source 34 (illustrated diagrammatically), an electric power source 36 (illustrated diagrammatically), and a cooling and irrigating fluid source 38 (illustrated diagrammatically), and a monitor 46 (illustrated diagrammatically), which may be necessary or desirable for conducting and monitoring the progress of a treatment using the catheter 10. The light source 34 may be, for example, a lamp (not shown). The lamp is adapted to provide light to a fiber optic waveguide 40 (see, for example, Figs. 2 and 4) which extends substantially the full length of the catheter 10 to a lens 48 adjacent the distal end 22 of the catheter 10.

Another fiber optic waveguide 42 is provided to transmit images back along the length of the catheter 10 from a lens 44 on the distal end 22 of the fiber optic waveguide 42 to the proximal end 20. The monitor 46 converts the returned image into a display for use by the treating physician in monitoring the progress of the treatment. The light source 34 can also be a power supply coupled by electrical conductors through, for example, lumen 26 of the catheter 10 to an LED positioned, for example, where lens 48 is positioned in Fig. 2, adjacent the distal end 22 of the catheter 10, to illuminate the treatment field and provide sufficient reflections to be transmitted via lens 44 and waveguide 42 to monitor 46. The monitor system 44, 42, 46 could also be, for example, a solid state imaging device, such as a charge coupled device, or the like, or any other suitable mechanism for producing on the monitor 46 a suitably high resolution image of the progress of treatment.

As best illustrated in Figs. 1 and 2, a region 50 of the catheter 10 adjacent the distal end 22 of the catheter 10 is provided with a number, illustratively three or four, of small ultrasound transducers 30 capable of transmitting sufficient power at appropriate frequencies for ultrasound visualization and therapy. The transducers 30 are best illustrated in Figs. 2, 4, 6 and 7. The transducers 30 lie adjacent each other in an array extending along the longitudinal extent of the catheter 10. As best illustrated in Fig. 6, conductors 54 through which each transducer 30 can be separately controlled extend through lumen 26.

The transducer(s) 30 may be of the types illustrated and described in U.S. Patent No. 5,117,832 or WO 99/49788, or any other suitable type. The therapeutic ultrasound is at frequencies and powers capable of achieving treatment by one or both of cavitation-induced tissue destruction and high intensity focused ultrasound hyperthermia (HIFU). Treatment of, for example, diseased prostate tissue 18, with HIFU results in necrosis of the treated prostate tissue 18 with the ultimate result that the treated tissue 18 is reabsorbed and/or discarded by the body over a period of several weeks to several months. Focal points 58 are the geometric foci of the transducers 30 illustrated in Fig. 2. By movement of the catheter 10, the focal points 58 of each transducer 30 may be moved for treatment of other areas of the diseased prostate tissue 18. Additionally, the drive signals to the transducers 30 can be phased in known manner to vary the effective focus of the array of transducers 30.

Further, if segmented transducers 30 of the type illustrated in, for example, WO 99/49788 are used in some one or more of the illustrated positions, the effective focus of each such segmented transducer 30 can be altered by appropriately phasing the drive signals to the various segments of that respective transducer, and the composite focus of the array of transducers 30 can be altered as well. The net effect of effective HIFU treatment of diseased prostate tissue 18 is that the patient experiences progressively better and better urine flow over the period while reabsorption of the necrosed tissue progresses until all of the necrosed prostate tissue 18 has finally been reabsorbed and recovery is complete. A means, such as the thermocouple(s) 60 illustrated in Fig. 4, can be provided adjacent the transducer(s) 30 for monitoring the temperatures adjacent the transducer(s) 30. This feedback can be helpful in treatment, but is also helpful to prevent damage to the transducer(s) 30 due to overheating. The conductors for coupling the thermocouples 60 to the control system for the transducers 30 can be provided along with conductors 54 in lumen 26.

Different ultrasound transducer excitation frequencies and powers can be employed which promote cavitation as the treatment modality, rather than HIFU. Cavitation is ordinarily conducted at somewhat lower excitation powers and frequencies, with frequencies typically ranging in the hundreds of kilohertz and powers in the watts per square centimeter to tens of watts per square centimeter range, as opposed to HIFU which is ordinarily conducted at frequencies ranging in the megahertz and powers in the hundreds of watts to kilowatts per square centimeter over short duty cycles.

If cavitation is the mechanism of treatment, the treated prostate tissue 18 is mechanically debrided by the formation and bursting of gas, for example, oxygen, nitrogen and the like, bubbles which form in the liquids, for example, blood and water, present in the tissue 18. Cavitation can also be promoted by "seeding," for example, by irrigating the treatment site with, for example, carbonated water instead of degassed water, or mixed with degassed water. The resulting tissue debris may remain at the debridement site. However, leaving the tissue debris there may result in further complications, and so, the catheter 10 may be provided with a mechanism for removal of the debris. One such mechanism is a lumen 62 in the catheter 10 coupled at its proximal end 20 to the cooling and irrigating fluid source 38. This source 38

may be, for example, a source of degassed water maintained at a temperature that permits its use not only as an irrigation medium for the treatment site, but also as a cooling medium for the transducer(s) 30. As the medium flows through the treatment field, as illustrated by arrows 64 in Fig. 2, the catheter 10 can be so configured that the medium flows over the transducer(s) 30, cooling it (them).

The irrigation/cooling medium also picks up debris and flushes the debris away, for example, through another lumen 66 provided in the catheter 10, or via the urethra 16 to the bladder 12, from which the debris may contemporaneously or later be evacuated, for example, by the application of a vacuum at the proximal end of a lumen 68, or by the patient emptying his bladder 12. If lumen 68 is provided in the catheter 10 for the evacuation of the debris-laden irrigation/cooling medium, this lumen 68 can be provided with a continuous vacuum 70 to assist in the removal of debris occasioned by the cavitation debridement.

The catheter 10's own visualization mechanism of the type described above, or a mechanism of the type described in, for example, the above referenced WO 99/49788, or X-ray or the like, may be used to determine the orientation of the transducer(s) 30 at the treatment site. Visualization can also be achieved by driving the ultrasound transducer(s) 30 in a pulse-echo mode to provide an ultrasound image of the progress of the treatment. The ultrasound image can be converted by known techniques into a video image on monitor 46. Such visualization mechanisms can permit the progress of the treatment to be monitored and controlled, regardless of the mechanism of treatment.

This visualization option is illustrated in Fig. 3. There, a switch 72 is provided to switch the power source, which may be, for example, a Focus Surgery, Inc., Sonablate™ model 500™ ultrasound driver/receiver, for driving the transducer(s) 30 from a therapy power source 74, which may be either a cavitation inducing power and frequency power source or a HIFU therapy power source, as previously discussed, to a pulse-echo mode power supply 76 which sends out high frequency visualization pulses into the tissue 18 being treated, receives the echoes from the tissue 18, and then converts the received echoes into one or more images in one or more known formats, for example, A mode, B mode, M mode, and so on, of the tissue 18 under treatment for display on the monitor 46. A feedback loop

incorporating, for example, a PC (not shown), can also be employed to modulate the power supplied to the transducer(s) 30 as a result of the visualized progress of the treatment. If the transducer arrangement illustrated in Fig. 5 is used, standard beamforming techniques can be used to generate true two dimensional (2-D) images.

The transducer(s) 30 itself (themselves) may be (a) non-segmented type, as shown in Figs. 2, 4, and 6, or a segmented type as illustrated in the above-identified WO 99/49788, or a segmented transducer 130, as shown, for example, in Fig. 5. When the segmented type transducer 130 is employed, the segments can be driven pairwise, groupwise, and/or sequentially to provide a variable depth of focus, a steerable ultrasound beam, and the like. A thermocouple, like thermocouples 60 illustrated in Fig. 4, for example, may also be provided for each segment, or for a group of segments, of the segmented transducer 130.

The catheter 10 can be of any of a number of suitable types. One such type may include braided catheters and those with braided sheaths to permit the transmission of torque down the length of the catheter 10. This aids in the manipulation of the distal end 22 of the catheter 10 into various orientations necessary for effective visualization and therapy. As illustrated in Fig. 6, a stiffening member 80 such as, for example, a thin metal strip, can be provided to transmit torque from the proximal end 20 to the distal end 22 of the catheter 10. By driving member 80, transducer(s) 30, 130 can be reaimed in order to treat a different tissue 18 volume. Member 80 can also serve as a ground conductor for the transducer(s) 30, 130, the light source 48 (if an LED at the distal end 22 is used as the light source), and so on. A lumen 82 is also provided for inflating fluid for the balloon 24 if the catheter 10 is provided with a balloon 24.

As shown in Figs. 8 and 9, the transducer(s) may also be (a) cylindrical, or part-cylindrical, type(s), which is (are) unfocused, for example, when the treatment modality is cavitation. Transducer 140 illustrated in Fig. 8 is cylindrical in shape and is used with the catheter 10 in the cavitation mode. Because the transducer 140 is cylindrical in shape, the wave which is produced by it propagates radially outward in all directions from its axis. Transducer 142 illustrated in Fig. 9 can also be used for cavitation. Transducer 142 has a part-circular, or sectoral, cross-section which can be used to propagate a cavitating ultrasound wave radially outward

from its axis through a somewhat pie-shaped sector of tissue. The ultrasound wave produced by transducer 142 is similarly unfocused. The transducers 140, 142 will typically extend coaxially with the catheter 10, but that is not essential to practice the invention.

Fig. 7 illustrates another catheter cross sectional configuration. In this configuration, a catheter 10 is closed in the region 50 of the catheter 10 where the transducer(s) 30, 130, 140, 142 is (are) mounted. A cavity 144 is thus provided for the transducer(s) 30, 130, 140, 142. This mechanically isolates the transducer(s) 30, 130, 140, 142 somewhat from the tissue 18, providing some greater measure of protection for both the catheter 10 and tissue 18 from unintended damage by the other. The covering over the transducer(s) 30, 130, 140, 142 in region 50 is of a type that permits propagation of the HIFU through it with minimal attenuation and minimal distortion of the ultrasound beam.

The cooling fluid flows from source 38 through a lumen as described above to the cavity 144. If the same cooling fluid is to be used for irrigation, of course, openings (not shown) can be provided for the flow of the fluid from the cavity 144 outward into the urethra 16 and/or the bladder 12. The cooling fluid runs through cavity 144 over transducer(s) 30, 130, 140, 142, and, where it is (they are) present, thermocouple(s) 60 in order to maintain the temperature(s) of the transducer(s) 30, 130, 140, 142 at (an) appropriate level(s). The cooling and irrigation fluid, or whatever portion of it is not exhausted into the tissue 18 to flush out debrided tissue, is then removed from the catheter 10 through lumen 66. Electrical service is provided for the transducer(s) 30, 130, 140, 142, thermocouple(s) 60, LED 48 (where an LED 48 is employed as the light source), and all other electrical requirements, through lumen 26. Finally, lumen 82 is provided to inflate and deflate balloon 24, where balloon 24 is present.

CLAIMS:

1. A method of treating tissue including (a) providing a catheter having proximal and distal ends, a lumen extending between the proximal and distal ends, multiple ultrasound transducers adjacent the distal end, the transducers capable of transmitting sufficient power for high intensity focused ultrasound (HIFU) therapy, and a device for monitoring the temperature adjacent the transducers, (b) orienting the transducers adjacent the treatment region, (c) exciting the transducers to treat the tissue, and (d) flushing fluid over the transducers.

2. The method of claim 1 wherein providing the transducers includes providing transducers capable of transmitting sufficient power to achieve treatment by at least one of HIFU-induced tissue ablation and cavitation.

3. The method of claim 2 wherein providing the transducers includes providing transducers capable of transmitting sufficient power to achieve treatment by HIFU-induced tissue ablation, the method further including permitting the treated tissue to be reabsorbed by the body.

4. The method of claim 2 wherein providing the transducers includes providing transducers capable of transmitting sufficient power to achieve treatment by cavitation, and (c) exciting the transducers to treat the tissue includes mechanically destroying the treated tissue by cavitation.

5. The method of claim 1 wherein (a) providing a catheter includes providing a second lumen through the catheter between the proximal and distal ends, the method further including applying a vacuum to remove fluid.

6. The method of claim 1 further including discharging the fluid into the body of the patient whose tissue is undergoing treatment.

7. The method of claim 1 wherein (a) providing a catheter further includes providing an optical fiber which extends to the distal end of the catheter and providing a light source adjacent the distal end of the catheter.

8. The method of claim 7 wherein providing a light source adjacent the distal end of the catheter includes providing a second optical fiber which extends between the proximal and distal ends of the catheter and providing a light adjacent the proximal end of the catheter.

9. The method of claim 7 wherein providing a light source adjacent the distal end of the catheter includes providing a light emitting diode (LED) adjacent the distal end, providing an electrical source, and providing conductors between the electrical source and the LED.

10. The method of claim 1 further including driving at least one of the transducers in a visualization mode to provide an ultrasound image of the progress of the treatment.

11. The method of claim 10 wherein driving at least one of the transducers in a visualization mode includes driving at least one of the transducers in a pulse-echo mode to provide an ultrasound image of the progress of the treatment.

12. The method of claim 10 further including converting the ultrasound image into a video image.

13. The method of claim 1 wherein (a) providing a catheter includes providing a braided catheter.

14. The method of claim 1 wherein (a) providing a catheter includes providing a catheter with a braided sheath.

15. The method of claim 1 wherein (a) providing a catheter includes providing a catheter with a stiffening member.

16. The method of claim 1 wherein (a) providing a catheter including a device for monitoring the temperature adjacent the transducers includes providing in the catheter a thermocouple oriented adjacent the transducers.

17. The method of claim 1 wherein (a) providing a catheter having multiple ultrasound transducers adjacent its distal end includes providing at least one segmented transducer.

18. The method of claim 1 wherein (a) providing a catheter having multiple ultrasound transducers adjacent its distal end includes providing at least one part-cylindrical transducer.

19. The method of claim 1 wherein (a) providing a catheter includes providing a catheter including an opening adjacent its distal end, providing the transducers adjacent the opening so that, when excited, the transducers radiate energy through the opening, and providing a fluid-impermeable, sonolucent covering

over the opening to retain fluid in the catheter while permitting ultrasound energy to pass from the catheter and return to the catheter.

20. Apparatus for treating tissue including a catheter having proximal and distal ends, a lumen extending between the proximal and distal ends, multiple ultrasound transducers adjacent the distal end, the transducers capable of transmitting sufficient power for high intensity focused ultrasound (HIFU) therapy, a device for monitoring the temperature adjacent the transducers, at least one transducer driver for exciting the transducers to treat the tissue, and a source providing a flow of fluid through the lumen and over the transducers.

21. The apparatus of claim 20 wherein the transducers are capable of transmitting sufficient power to achieve treatment by at least one of HIFU-induced tissue ablation and cavitation.

22. The apparatus of claim 21 wherein the transducers are capable of transmitting sufficient power to achieve treatment by HIFU-induced tissue ablation.

23. The apparatus of claim 21 wherein the transducers are capable of transmitting sufficient power to achieve treatment by cavitation.

24. The apparatus of claim 20, the catheter further including a second lumen extending between the proximal and distal ends, and means for applying a vacuum to the proximal end of the second lumen to recover fluid.

25. The apparatus of claim 20 further including an opening from the first lumen adjacent the distal end permitting discharging of the fluid into the body of the patient whose tissue is undergoing treatment.

26. The apparatus of claim 20 further including an optical fiber which extends to the distal end of the catheter and a light source adjacent the distal end of the catheter.

27. The apparatus of claim 26 wherein the light source includes a second optical fiber which extends between the proximal and distal ends of the catheter and a light adjacent the proximal end of the second optical fiber.

28. The apparatus of claim 26 wherein the light source includes a light emitting diode (LED) adjacent the distal end, an electrical source, and conductors which extend between the electrical source and the LED.

29. The apparatus of claim 20 wherein the at least one transducer driver includes a driver for driving at least one of the transducers in a visualization mode to provide an ultrasound image of the tissue.

30. The apparatus of claim 29 wherein driver for driving at least one of the transducers in a visualization mode includes a driver for driving the at least one of the transducers in a pulse-echo mode to provide an ultrasound image of the tissue.

31. The apparatus of claim 29 further including an image converter for converting the ultrasound image into a video image.

32. The apparatus of claim 20 wherein the catheter includes a braided catheter.

33. The apparatus of claim 20 wherein the catheter includes a braided sheath.

34. The apparatus of claim 20 wherein the catheter includes a stiffening member.

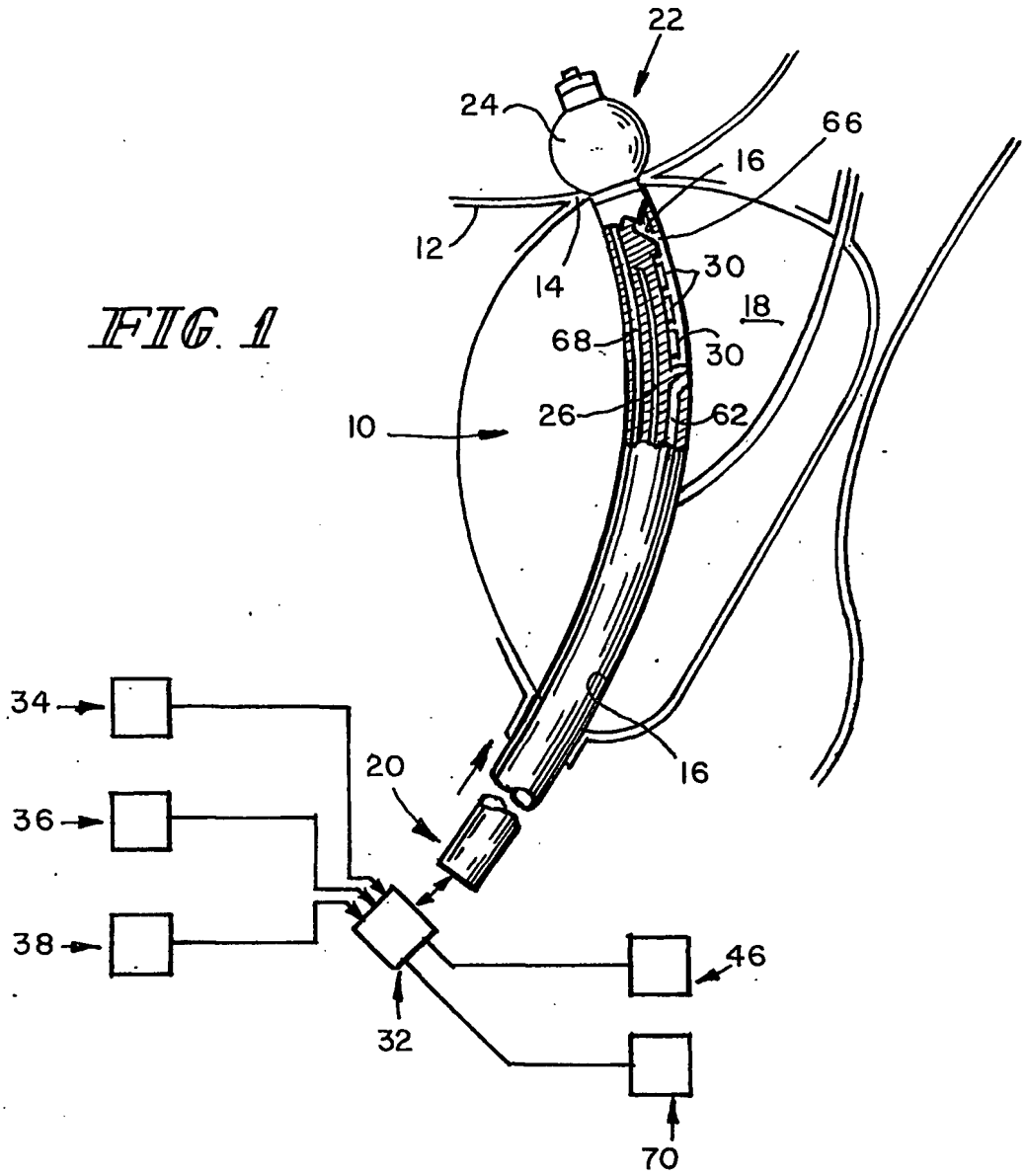
35. The apparatus of claim 20 wherein the device for monitoring the temperature adjacent the transducers includes a thermocouple oriented adjacent the transducers.

36. The apparatus of claim 20 wherein the multiple transducers include at least one segmented transducer.

37. The apparatus of claim 20 wherein the multiple transducers include at least one part-cylindrical transducer.

38. The apparatus of claim 20 wherein the catheter includes an opening adjacent its distal end, the transducers being oriented adjacent the opening so that, when excited, the transducers radiate energy through the opening, the apparatus further including a fluid-impermeable, sonolucent covering over the opening to retain fluid in the catheter while permitting ultrasound energy to pass from the catheter and return to the catheter.

FIG. 1



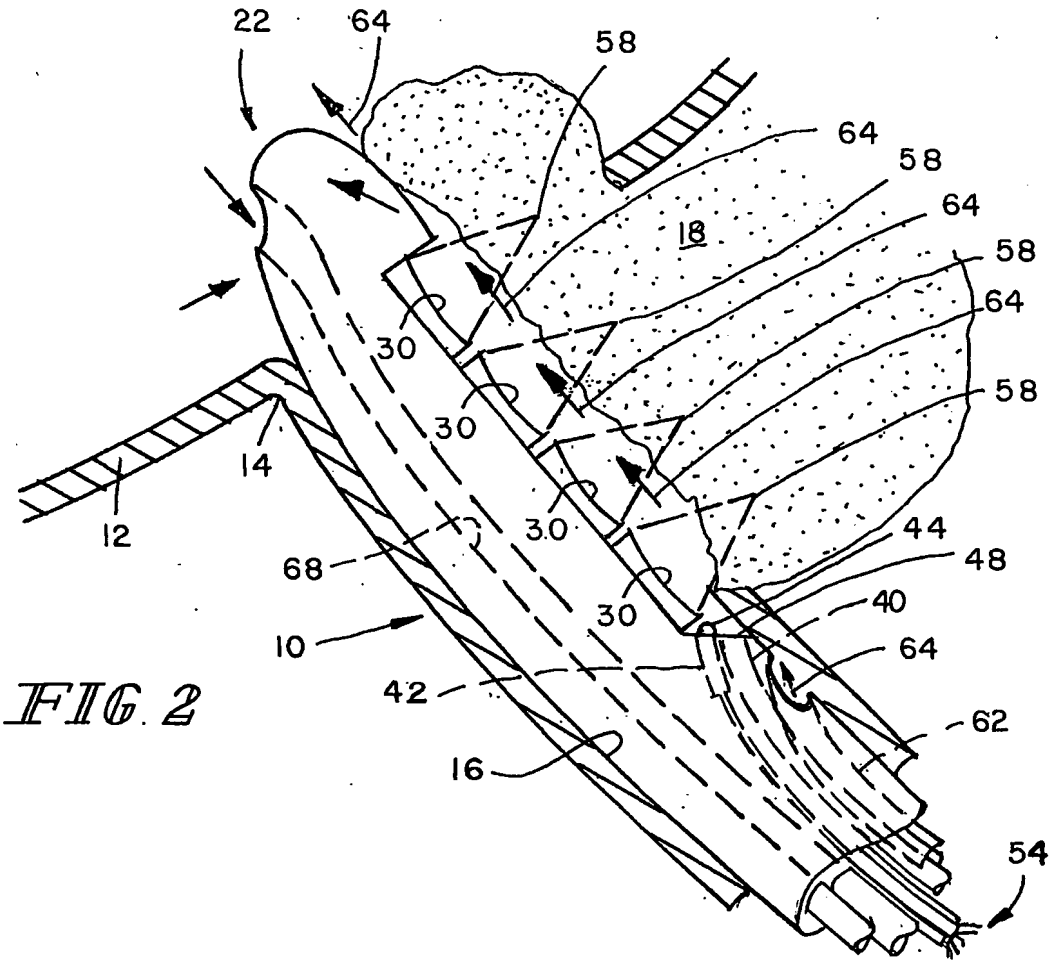

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FIG. 2

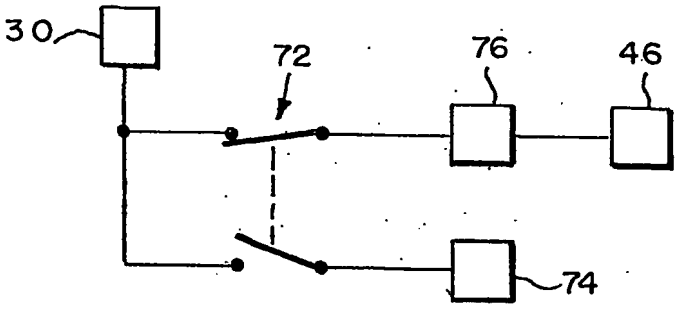
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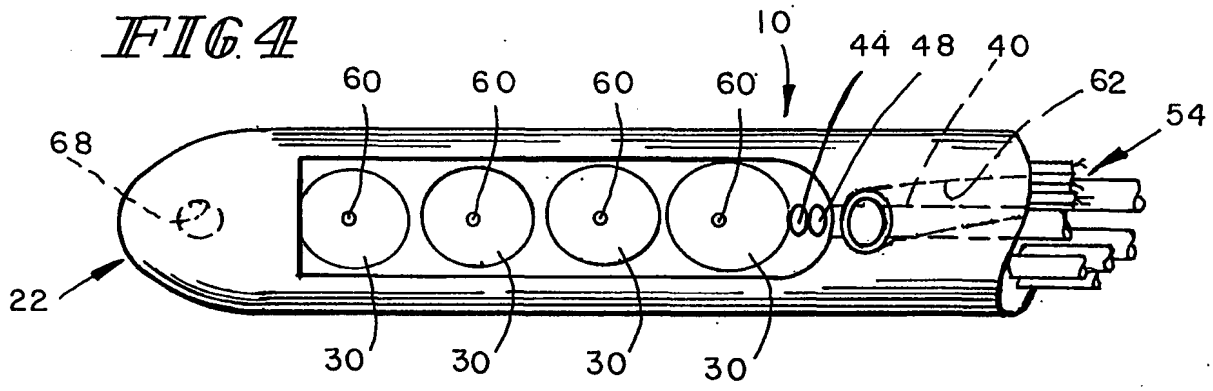
FIG. 3

FIG. 4



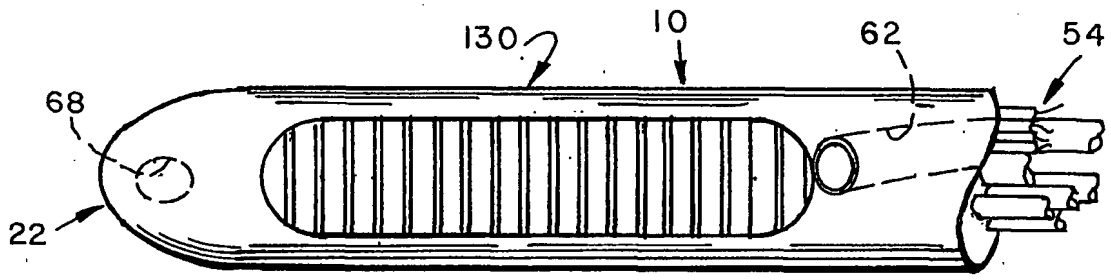


FIG. 5

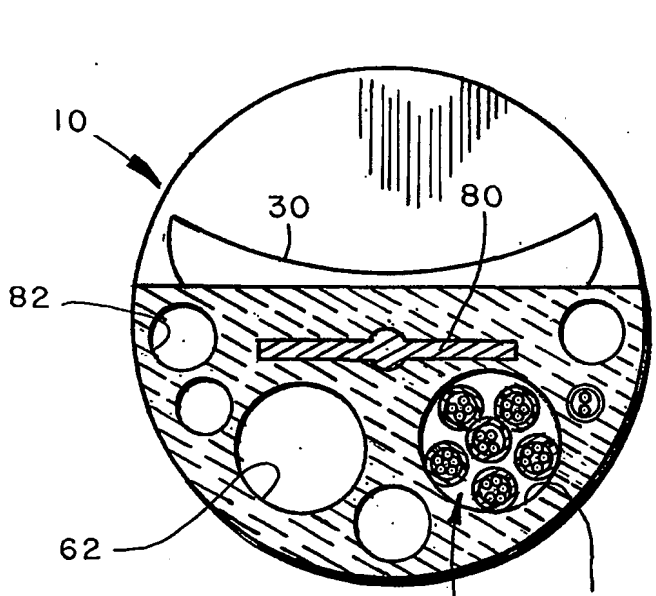


FIG. 6

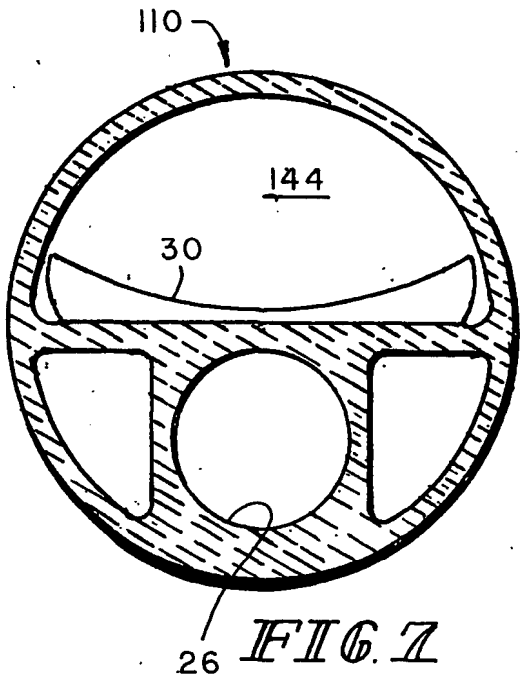


FIG. 7

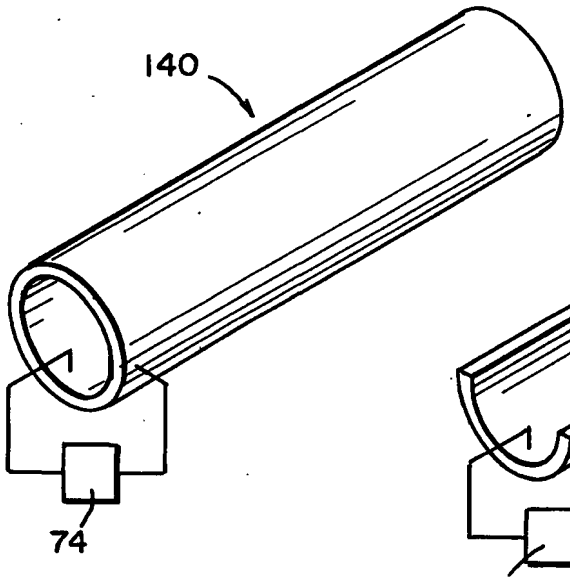


FIG 8

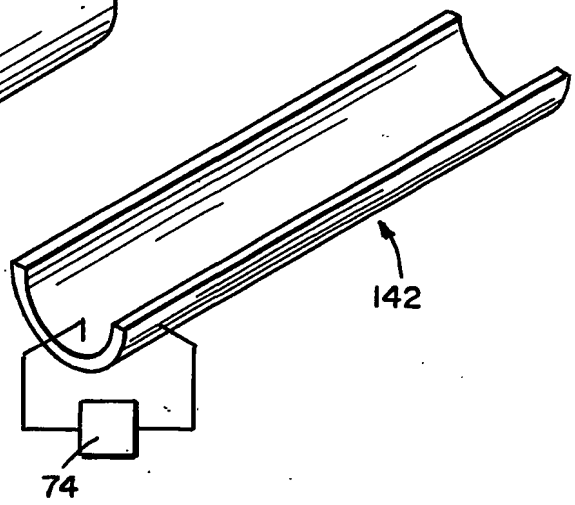


FIG 9